

### REMARKS

Claims 29-34 have been added and claims 2, 3, 13, 14 and 17 have been cancelled. Thus, claims 1, 4, 7, 9, 10, 15, 16, 18 and 22 have been amended. Claims 1, 4-12, 15, 16 and 18-34 are now pending in the present application. No new matter has been added. In view of the above amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 1-6, 13 and 14 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,524,805 to Hoffman. 8/25/05 Office Action, p. 2.

Amended claim 1 recites a valve comprising "*a first flexible member formed as a first sheet of polymeric material* including first and second flaps separated from one another by a first slit, the first and second flaps moving, when subjected to a fluid pressure of at least a predetermined threshold level, to an open position so that material may flow past the first flexible member through a first lumen of the catheter, the first and second flaps remaining closed at all times when a fluid pressure exerted thereagainst is less than the threshold level to prevent flow through the first lumen" and "*a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position.*"

In contrast, Hoffman describes a duckbill valve 10 which allows fluid flow in only one direction. Thus, it is respectfully submitted that Hoffman neither shows nor describes "*a first flexible member formed as a first sheet of polymeric material* including first and second flaps separated from one another by a first slit, the first and second flaps moving, when subjected to a fluid pressure of at least a predetermined threshold level, to an open position so that material may flow past the first flexible member through a first lumen of the catheter, the first and second flaps remaining closed at all times when a fluid pressure exerted thereagainst is less than the threshold level to prevent flow through the first lumen" and "*a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position,*" as recited in claim 1.

Furthermore, it is respectfully submitted that the duckbill shape of the valve 10 is specifically chosen by Hoffman so that fluid pressures in a direction opposite that of permitted fluid flow force sealing lips 20, 22 against one another. Hoffman, col. 4, ll. 35-51. Forming the valve 10 as a "sheet of polymeric material" as recited in the claims would eliminate this

enhanced sealing action which actually increases the sealing force of the valve 10 of Hoffman as a reverse pressure is increased. Thus, it is respectfully submitted that replacing the valve 10 of Hoffman with a valve formed of a sheet of polymeric material would frustrate the purpose of the valve of Hoffman. That is, the shape of the valve 10 of Hoffman was specifically designed so that as a reverse fluid pressure applied thereto is increased, the sealing pressure urging the lips 20 and 22 against one another is increased to prevent backflow through the valve 10. Thus, it is respectfully submitted that Hoffman teaches away from *"first flexible member formed as a first sheet of polymeric material,"* as recited in claim 1 and that claim 1 is allowable for this reason.

Because claims 4-6 depend from and, therefore, include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claims 7 and 8 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Hoffman in view of U.S. Patent No. 3,621,557 to Cushman et al. ("Cushman"). 8/25/05 Office Action, p. 2.

Initially it is respectfully submitted that, as forming the valve 10 of Hoffman as claimed would frustrate the purpose of the valve 10, Hoffman teaches away from a valve as recited and one skilled in the art would not be motivated to combine Hoffman with Cushman or any other reference to eliminate the duckbill shape of the valve 10.

Furthermore, it is respectfully submitted that Cushman describes an insert for a sandwich panel including a skin sheet 26 which is designed to remain sealed at all times regardless of a fluid pressure to which it is subjected. The slit 70 in the sheet 26 opens only when a needle is inserted therethrough to inject potting material and even when the needle 26 is inserted through the slit 70, the sheet 26 seals around the needle to prevent the material from passing through the sheet 26. *Cushman*, col. 4, ll. 23-27. In addition, the spring 46 of the sandwich panel does not serve to close the slit 70 or any other valve. Rather, the spring 46 merely maintains the position of the insert while the needle is inserted through the slit 70. *Id.* Thus, it is respectfully submitted that Cushman neither shows nor suggests *"the first and second flaps moving, when subjected to a fluid pressure of at least a predetermined threshold level, to an open position so that material may flow past the first flexible member through a first lumen of the catheter"* and *"a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position,"* as recited in claim 1 and that claim 1 is allowable.

It is respectfully submitted that claims 7 and 8, which depend from, and, therefore include

the limitations of claim 1, are also allowable.

Claims 9-11, 15-18, 22-24, 26 and 27 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Hoffman in view of U.S. Patent No. 5,810,789 to Powers et al. ("Powers"). 8/25/05 Office Action, pp. 3-4.

As described above, it is respectfully submitted that Hoffman teaches away from the claimed invention as forming the valve 10 of Hoffman as claimed would frustrate the purpose of the valve 10 and, therefore, one skilled in the art would not be motivated to combine Hoffman with Powers or any other reference to eliminate the duckbill shape of the valve 10.

Furthermore, it is respectfully submitted that Powers describes a vascular access catheter with a valve 176 including a slit 178 but neither shows nor suggests any additional element to aid in closing the slit 178. Thus, it is respectfully submitted that Powers is insufficient to cure the above-described deficiencies of Hoffman, and that neither Hoffman nor Powers, either alone or in combination, discloses or suggests "*a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position,*" as recited in claim 1.

Amended claim 16 recites limitations substantially similar to those of claim 1, including "a valve mounted within the housing flow passage to selectively restrict flow of materials therethrough, the valve being formed as *a sheet of polymeric material* and including: first and second flaps of the sheet separated from one another by a first slit in the sheet, the first and second flaps opening when a pressure applied to the valve is at least a threshold pressure and remaining closed when the pressure applied thereto is less than the threshold pressure" and "*a first biasing member coupled to the valve, the biasing member biasing the first and second flaps to the closed portion.*" Thus, it is respectfully submitted that claim 16 is allowable for at least the reasons stated above with reference to claim 1. Because claims 18, 22-24, 26 and 27 depend from, and, therefore include the limitations of claim 16, it is respectfully submitted that these claims are also allowable.

Claims 19-21 and 28 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Hoffman in view of Cushman and in further view of Powers. 8/25/05 Office Action, pp. 4-5.

It is respectfully submitted that, for the reasons stated above, neither Hoffman, nor Cushman nor Powers, either alone or in combination, discloses or suggests "*a first biasing*

*member coupled to the valve, the biasing member biasing the first and second flaps to the closed position,"* as recited in claim 16. Accordingly, it is respectfully submitted that claims 19-21 and 28 are allowable for at least the reasons described above with reference to claim 16.

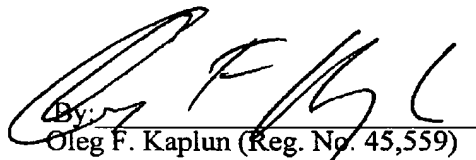
Because new claims 29 - 34 depend from, and, therefore include the limitations of claims 1 and 16, it is respectfully submitted that these claims are also allowable.

Applicants also wish to bring to the Examiner's attention that although claims 1-28 are indicated as being rejected in the Office Action Summary, no explanation was provided for the rejection of dependent claims 12 and 25.

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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